

REMARKS/ARGUMENTS

Claims 1-2 and 4-5 have been amended by deleting the word "prevention." Claim 1 has also been amended to recite a composition comprising a Moutan root bark extract and one or more specific compounds wherein the composition has an antifungal and antibacterial activities against *Trichophyton mentagrophytes*, *Trichophyton rubrum*, *Candida albicans*, *Epidermophyton floccosum*, *A. niger*, and *P. citrinum*. Claim 4 has also been amended to recite that the composition comprises a spray. Claim 5 has also been amended to recite the composition comprises at least one of a medicine, a cleansing agent, or a cosmetic. Claim 6 has been amended to recite a composition for the treatment of osmidrosis caused by *Stenotrophomonas maltophilia* and *Candida albicans*. Claims 7 and 8 have both been amended to recite a composition for the treatment of osmidrosis. Claim 8 has also been amended to recite that the composition comprises at least one of a spray, a liquid, a solution, a stick, a gel, a cream or a cleansing agent. Claim 12 has been amended by deleting the compounds Miconazole, Clotrimazole, Nystatin, Tolnaftate, and Triclosan. Claim 12 has also been amended to clarify that the anti-microbial composition has an anti-microbial activity against the recited microorganisms. Furthermore, claim 12 was amended by deleting *Streptococcus mutans*. Claim 13 has been amended to clarify the recited ratio range of 1:5 to 5:1 by weight. Claim 15 has been amended by deleting the 0.001 to 20% range and by clarifying that the percentage ranges recited for each element are based on the weight of the anti-microbial composition. Claim 19 has been amended to correct typographical errors. Support for these amendments is found throughout the application as filed. Claims 3, 9-11, 21 and 23 have been cancelled.

I. Brief Summary of the Currently Claimed Compositions

Independent claim 1 recites a composition for the treatment of athlete's foot, comprising a Moutan root bark extract as an active ingredient, and further comprising one or more compounds selected from the group consisting of Ketoconazole, Itraconazole, Fluconazole, Fenticonazole, Econazole, Bifonazole, Oxiconazole, Cloconazole, Rolcyclate, Amphotericin B, Flucytosine, Griceofulvin, Terbinafine, Naftifine, Haloprogin and Ciclopirox, wherein the composition has an antifungal and antibacterial activities against *Trichophyton mentagrophytes*, *Trichophyton*

rubrum, *Candida albicans*, *Epidermophyton floccosum*, *A. niger*, and *P. citrinum*. Independent claim 6 recites a composition for the treatment of osmidrosis caused by *Stenotrophomonas maltophilia* and *Candida albicans*, comprising a Moutan root bark extract as an active ingredient.

Furthermore, the currently claimed compositions are capable of obtaining a synergistic effect, as exemplified in the examples, of the medicines by mixing one or more compounds selected from the group consisting of Ketoconazole, Itraconazole, Fluconazole, and the like, and terbinafine, etc. with the Moutan root bark extract, in order to improve antifungal effects.

Thus, the currently claimed compositions for the treatment of athlete's foot have excellent antifungal effects against athlete's-foot-causing pathogens (*Trichophyton mentagrophytes*, *rubrum*), and skin eczema-causing pathogens (*Candida albicans*, *Epidermophyton floccosum*). In addition, the currently claimed compositions for osmidrosis treatment have superior deodorizing effects against many smell-inducing bacteria or pathogens, in particular *Stenotrophomonas maltophilia*. Furthermore, the currently claimed anti-microbial compositions have superior anti-microbial activity against the bacteria recited in Claim 12.

II. Rejections under 35 U.S.C. §112

Claims 1-8 stand rejected under 35 U.S.C. §112, first paragraph, for not being enabled for "preventing" athlete's foot or osmidrosis. Accordingly, claims 1, 2, and 4-5 have been amended by deleting the word "prevention." Claim 3 has been cancelled. Claims 6-8 have been amended by deleting the term "prevention" and replacing it with "treatment." As currently amended, claims 6-8 recite the treatment of osmidrosis. Therefore, Applicants submit that the rejections under 35 U.S.C. §112, first paragraph, have been overcome and request withdrawal of rejections.

Claims 4, 8 and 12-22 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

In particular, claims 4 and 8 stand as being indefinite due to the phrase "is applied in the form of sprays..." and the recitation of plural terms (i.e. sprays). Claims 4 and 8 have been amended by deleting the phrase "is applied in the form..." and to recite singular terms (i.e. a

spray). Specifically, claim 4 has been amended to recite the composition of claim 1, wherein the composition comprises a spray. Similarly, claim 8 has been amended to recite the composition of claim 6, wherein the composition comprises at least one of a spray, a liquid, a solution, a stick, a gel, a cream, or a cleansing agent.

Claim 12 stands as being indefinite due to the phrase “wherein the anti-microbial composition has an anti-microbial for.” Accordingly, claim 12 has been amended to recite that the anti-microbial composition has an anti-microbial activity against the recited microorganisms.

Claims 13 stands as being indefinite because it is unclear as to the compounds contemplated by the ratio of “1:5 to 5:1 by weight”. Claim 13 has been amended to clarify that the recited ratio range comprises the ratio of Moutan root bark extract and at least one anti-microbial compound. For example, if the composition comprises Moutan root bark extract and only one anti-microbial then the ratio is that of Moutan root bark extract to the anti-microbial. Further, if the composition comprises Moutan root bark extract and two anti-microbial compounds then the ratio is that of Moutan root bark extract to the sum of the two anti-microbial compounds.

Claim 15 stands as being indefinite due to the phrase “said compounds in an amount of 0.001 to 20%” and because it is unclear as to the basis of the recited percentage ranges recited for each element (e.g. skin moisturizer). Accordingly, claim 15 has been amended by deleting the phrase “said compounds in an amount of 0.001 to 20%” and to clarify that the recited percentages are based on the weight of the anti-microbial composition.

Claim 21 stands as being indefinite due to the phrase “wherein said filler is liquefied propane gas.” Claim 21 has been cancelled.

In light of the current amendments and foregoing statements, Applicants respectfully submit that all of the rejections under 35 U.S.C. §112, second paragraph, have been overcome. Therefore, Applicants request the withdrawal of all rejections under 35 U.S.C. §112, second paragraph.

III. Rejections under 35 U.S.C. §102(b)

Claims 1, 2, 5-11 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by JP 58023612 to Uchida et al. (hereinafter "Uchida") or alternatively by JP 10194916 to Mori et al. (hereinafter "Mori").

To establish an anticipation, a prior art reference must disclose the invention as set forth in the claim. Specifically, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131 citing *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As also set forth in M.P.E.P. §2131, "The identical invention must be shown in as complete detail as is contained in the ...claim." See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicant respectfully submits that neither Uchida nor Mori teach each and every element of the currently claimed invention. Specifically, for reasons discussed below, neither reference discloses a composition including a Moutan root bark extract and at least one of the antifungal compounds recited in independent claim 1. Likewise, neither reference discloses a composition suitable for treating osmidrosis caused by *Candida albicans* as recited in independent claim 6. Since neither reference teaches each and every element recited in claims 1 and 6, neither Uchida nor Mori anticipate independent claims 1 and 6 or any claims dependent thereon.

Uchida is generally directed to a cosmetic composition including a Mouton root bark extract, wherein the continued use of the composition exhibits improvements for skin roughening, lever-spots, ephelis, pimples, itching etc. Uchida discloses a general procedure for extracting root bark with either water or alcohol. However, Uchida is completely silent regarding compositions including a Moutan root bark extract and at least one of the antifungal compounds recited in claim 1. Since Uchida fails to disclose a composition including the combination of a Moutan root bark extract and an antifungal, much less one of the currently recited antifungals, the compositions disclosed by Uchida do not exhibit anti-mold effects (antifungal effects). Therefore, the compositions, lacking an antifungal compound, disclosed by Uchida do not exhibit antifungal activity against *Candida albicans* as recited in independent claims 1 and 6. As evident by their different properties, the compositions disclosed by Uchida

are quite different than the currently claimed compositions. Simply stated, Uchida does not disclose each and every element as currently claimed.

Mori is directed generally to a cosmetic including a Moutan root bark extract. In particular, Mori is directed to providing cosmetic compositions having antimicrobial action while not irritating or sensitizing the skin. The compositions proposed by Mori include a Moutan root bark extract with "one or two or more kinds of compound selected from a polyhydric alcohol and an alkyl ether of the polyhydric alcohol..." Like Uchida, Mori is silent regarding compositions including a Moutan root bark extract and at least one of the antifungal compounds recited in claim 1. Since Mori fails to disclose a composition including the combination of a Moutan root bark extract and an antifungal, much less at least one of the currently recited antifungals, the compositions disclosed by Mori do not exhibit anti-mold effects (antifungal effects). Therefore, Mori's compositions, lacking antifungal compounds, do not exhibit any antifungal activity against *Candida albicans* as recited in independent claims 1 and 6. Similar to Uchida, the compositions disclosed by Mori are quite different than the currently claimed compositions, evident by their different properties. Likewise, Mori simply does not disclose each and every element as currently claimed.

For the reasons discussed above, Applicants respectfully submit that neither Uchida nor Mori teach each and every element of the currently claimed invention. Therefore, independent claims 1 and 6, as well as all claims dependent thereon, are not anticipated by the cited references. Applicants request the withdrawal of the rejections under 35 U.S.C. §102(b).

IV. Rejections under 35 U.S.C. §103(a)

Claims 1-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0058010 to Picard-Lesboueyries et al. (hereinafter "Picard") and Uchida in view of U.S. Patent No. 5,296,472 to Sanchez et al. (hereinafter "Sanchez"). Claims 1-22 are also rejected under 35 U.S.C. §103(a) as being unpatentable over Mori and JP 09158042 to Nishibe et al. (hereinafter "Nishibe"), in view of Picard, and further in view of Sanchez.

To establish a prima facie case of obviousness the prior art references must teach or suggest all the claim elements. Furthermore, the teaching or suggestion to make the claimed

invention must be found in the prior art, not in applicant's disclosure. The Office has not proven a *prima facie* case of obviousness because the references cited do not teach or suggest each and every claimed element.

Picard is directed to foaming compositions for the treatment of greasy skin or acne-prone skin. The compositions contemplated by Picard include an extract of Moutan root, a surfactant system to provide good foaming characteristics. Picard indicates that other antimicrobials and adjuvants typically found in cosmetic products may optionally be included in the foaming compositions disclosed. Picard provides merely a generalized statement that antimicrobial agents may be chosen from antibiotics and antifungal agents. It should be noted that Picard's teachings are directed to treatment of acne-prone skin. As is well known, acne involves follicles, often called pores, becoming blocked. More specifically, sebum (oil) which normally drains to the surface gets blocked and bacteria starts to grow. Since antifungals treat fungal infections and not bacterial infections, of which Picard is concerned, Picard's focus on essentially treating bacterial growth would not reasonably include the use of antifungals, much less the antifungals recited in claims 1 and 12. Accordingly, compositions contemplated by Picard simply lack the synergistic antifungal effect against *Candida albicans* (and other microorganisms) as recited in independent claims 1, 6 and 12. Therefore, Picard does not teach or suggest each and every element of claims 1, 6, or 12.

As discussed above, Uchida is directed to a cosmetic composition including a Mouton root bark extract, wherein the continued use of the composition exhibits improvements for skin roughening, lever-spots, ephelis, pimples, itching etc. However, Uchida is silent regarding the desirability of formulating compositions including a Moutan root bark extract and an antifungal compound, much less one of the antifungal compounds recited in claims 1 and 12. Accordingly, all compositions contemplated by Uchida do not include antifungal compounds and thus also do not exhibit anti-mold effects (antifungal effects). Therefore, Uchida's compositions, lacking antifungal compounds, do not exhibit any antifungal activity against *Candida albicans* (and other microorganisms) as recited in independent claims 1, 6 and 12. Therefore, Uchida does not teach or suggest each and every element of claims 1, 6, or 12.

Sanchez is directed to providing methods for delipidation of skin or hair by using cyclodextrins and derivatives thereof and for removing cerumen from the ear canal. The compositions contemplated by Sanchez are applied to skin/ear canal and allowed to complex with skin lipids or cerumen before being washed off. Sanchez only provides a generalized statement that compositions containing cyclodextrin can include an anti-microbial. At no point does Sanchez ever indicate using a Moutan root bark extract. Furthermore, Sanchez is completely silent regarding the desirability of formulating compositions including a Moutan root bark extract and an antifungal compound, much less one of the antifungal compounds recited in claims 1 and 12. Accordingly, all compositions contemplated by Sanchez do not include antifungal compounds and thus also do not exhibit anti-mold effects (antifungal effects). Therefore, Sanchez's compositions, lacking antifungal compounds, do not exhibit any antifungal activity against *Candida albicans* (and other microorganisms) as recited in independent claims 1, 6 and 12. Therefore, Sanchez does not teach or suggest each and every element of claims 1, 6, or 12.

As discussed above, Mori is directed to cosmetic compositions including a Moutan root bark extract. However, Mori is silent regarding the desirability of formulating compositions including a Moutan root bark extract and an antifungal compound, much less one of the antifungal compounds recited in claims 1 and 12. Accordingly, all compositions contemplated by Mori do not include antifungal compounds and thus also do not exhibit anti-mold effects (antifungal effects). Therefore, Mori's compositions, lacking antifungal compounds, do not exhibit any antifungal activity against *Candida albicans* (and other microorganisms) as recited in independent claims 1, 6 and 12. Therefore, Mori does not teach or suggest each and every element of claims 1, 6, or 12.

Nishibe is directed providing a textile treating agent including a Moutan root bark extract; wherein the textile treating agent is useful for preventing bacteria and mold breeding in / on textiles that causes deterioration, discoloration or embrittlement of the fiber and leading to the inflammation of the skin due to the textile product. See paragraph [0004]. More specifically, Nishibe discloses the use of Moutan root bark extract as a "processing agent of textiles." See paragraph [0006]. Similar to the other references cited, Nishibe is silent regarding the

desirability of formulating compositions including a Moutan root bark extract and an antifungal compound, much less one of the antifungal compounds recited in claims 1 and 12. Therefore, Mori's compositions, lacking antifungal compounds, do not exhibit any antifungal activity against *Candida albicans* (and other microorganisms) as recited in independent claims 1, 6 and 12. Therefore, Mori does not teach or suggest each and every element of claims 1, 6, or 12.

Since Picard, Uchida, Mori, Nishibe and Sanchez all fail to teach or suggest a composition including a Moutan root bark extract and an antifungal compound as recited in claims 1 and 12, any combination of these references also fails to teach or suggest each and every claimed element as recited in claims 1 and 12 or any claims dependent thereon. Likewise, since the cited references also fail to teach or suggest compositions capable of exhibiting antifungal activity against *Candida albicans*) as recited in claims 1, 6 and 12, any combination of these references also fails to teach or suggest each and every claimed element as recited in claims 1, 6 and 12 or any claims dependent thereon. In light of the foregoing statements, it is respectfully submitted that the rejections of all currently pending claims under 35 U.S.C. 103(a) have been overcome. Applicants request the withdrawal of the rejections under 35 U.S.C. §103(a).

V. Conclusion

In view of the current amendments and remarks made above, Applicants submit that the pending claims are in condition for allowance. Applicants respectfully request that the claims be allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

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therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John E. Johnson, III". The signature is fluid and cursive, with a horizontal line at the end.

John E. Johnson, III
Registration No. 58,367

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111
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